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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/468,673	12/21/1999	D LANSING TAYLOR	97223D	3907

20306 7590 12/19/2005

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER

LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/468,673

Applicant(s)

TAYLOR, D LANSING

Examiner

Leon Y. Lum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 30 September 2005 is acknowledged and has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al (US 5,846,708) in view of Cherukuri et al (US 5,980,704).

In the instant claims, Hollis et al reference teaches a sequencer 10 (i.e. base having a surface) with an array of test sites 12, wherein each test site contains a

plurality of probes 22 that bind to cell targets, and wherein probes in respective test sites differ in known sequence for simultaneous detection of a plurality of different targets (i.e. non-uniform micro patterned chemical array comprises multiple cell binding sites; more than one cell type). See column 4, lines 23-28 and 32-45; and Figure 1. In addition, Hollis et al reference teaches that test sites 12 contain channels (i.e. well) wherein the probes 22 are immobilized therein. See column 4, lines 34-35 and Figures 2-4. With respect to claims 16-17, although Hollis et al reference does not explicitly teach "a controlled array of cell types on the wells, wherein the cell type on an individual well is dependent upon the cell binding specificity of the cell binding sites in the well", since Hollis et al reference teaches that probes on each site can bind to different targets and that cells are targets, as stated above, it is necessarily required that different types of cells are present at each test site.

However, Hollis et al reference fails to teach a fluid delivery system, wherein said fluid delivery system comprises a chamber that mates with the base, wherein the chamber comprises a plurality of domains matching the wells on the surface of the base, and microfluidic channels that supply fluids to the domains.

Cherukuri et al reference teaches a modular configuration wherein the a center distribution plate with a plurality of reservoirs and microchannels (i.e. fluid delivery system comprises a chamber; microfluidic channels) is defined into a plurality of sectors, each sector being directly positioned above a reaction cell located on the bottom cell plate (i.e. comprises a plurality of domains matching the wells on the surface of the base; mates with the base), in order to provide a proper control and delivery

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system for regulating and distributing minute amounts of reagents to the reaction cells.

See column 2, lines 6-9; and column 3, lines 7-10 and 21-30.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Hollis et al to include a modular configuration wherein the a center distribution plate with a plurality of reservoirs and microchannels (i.e. fluid delivery system comprises a chamber; microfluidic channels) is defined into a plurality of sectors, each sector being directly positioned above a reaction cell located on the bottom cell plate (i.e. comprises a plurality of domains matching the wells on the surface of the base; mates with the base), as taught by Cherukuri et al, in order to provide a proper control and delivery system for regulating and distributing minute amounts of reagents to the reaction cells. The modular configuration of Hollis et al has the advantage of providing controlled means of reagent delivery to specific reaction cells, thereby providing motivation to combine the modular configuration with the device of Hollis et al. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the modular configuration of Cherukuri et al with the device of Hollis et al, since Hollis et al teach an array of reaction wells, and the microchannels of Cherukuri et al are capable of delivering fluid to a plurality of reaction wells.

With regards to claims 9 and 18, Cherukuri et al reference teaches reservoirs, as stated above. Although Cherukuri et al reference does not explicitly teach that the reservoirs are "raised", since the reservoirs are on a plate that is above the bottom cell

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plate, it is considered to be on a higher level than the bottom cell plate and are therefore raised.

With regards to claims 10 and 19, Cherukuri et al reference teaches that the center distribution plate contains overflow feeds 380 (i.e. microfluidic channels that remove excess fluid from the domains). See column 7, lines 16-21 and Figure 3.

With regards to claims 11 and 20, Cherukuri et al reference teaches column reservoirs coupled to microchannels (i.e. individual microfluidic channel) that deliver reagents to a location vertical from the column reservoirs, wherein column reservoirs are only capable of delivering its reagents to the reaction cells that are situated vertically from the column reservoirs, in order to permit a large array of parallel tests to be conducted simultaneously (i.e. supplies fluid to a single domain, to provide separate fluid flow to each domain). See column 3, lines 13-15 and column 8, lines 33-37.

With regards to claims 12 and 21, Cherukuri et al reference teaches a plurality of dams (i.e. plug) that prohibit reagents from entering a cell feed without the activation of miniature pumps, which allows reagents to be drawn over the dams from the microchannels and deposited into the reaction cells. See column 3, lines 24-30.

With regards to claims 13 and 22, Cherukuri et al reference teaches that the microchannels are etched on both sides of the center distribution plate (i.e. microfluidic channel extends from each domain to an edge of the chamber). See column 3, lines 7-10 and Figure 3.

With regards to claims 14-15, Hollis et al reference teaches an array of test sites 12 and that test sites differ in probes that bind to cells for simultaneous detection of a

plurality of different cell targets (i.e. array of cells on the wells; wells in total comprise cell binding site for more than one cell type), as stated above. See column 4, lines 23-24 and 37-45.

Response to Arguments

5. On pages 6-8 of the Remarks, filed 23 June 2005, Applicant traverses the rejection of claims 1 and 9-22 under 35 U.S.C. 103(a) over Hollis et al (US 5,846,708) in view of Cherukuri et al (US 5,980,704). Specifically, Applicant argues three points: (1) Applicant argues that the previous Office Action provided only a generalized statement of motivation to combine the references and has not provided either a line or reasoning as to why one of skill in the art would have found the invention obvious nor any factual support for the assertion of motivation to combine (see page 7, 3rd paragraph). Applicant also argues that neither reference provides any teaching, suggestion, or motivation to combine their respective teachings to arrive at the claimed invention (see page 8, 1st paragraph). (2) Applicant argues that the art cited by the previous Office Action is not within the field of endeavor since Hollis teaches a semiconductor chip, Cherukuri teaches a device for performing combinatorial synthetic chemistry, and neither reference "are concerned with cassettes for cell screening (see page 7, 4th paragraph). Applicant also argues that one of skill in the art would not look to a system for combinatorial synthetic chemistry in fashioning the claimed invention (see page 8, 1st paragraph). (3) Applicant argues that both Hollis and Cherukuri teach away from the

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present invention since the claimed invention requires a fluid delivery chamber that mates with the base, while Hollis teaches a microfluidic system that is adjacent to the array of test sites (see page 8, 2nd paragraph). In addition, Applicant contends that the teaching of Hollis where microfluidic channels deliver fluid to the entirety of the array contrasts with the claimed invention which requires microfluidic channels to supply fluid to “domains matching the wells of the base” (see page 8, 2nd paragraph). Furthermore, Applicant argues that Cherukuri teaches a device that is pretreated to eliminate surface adsorption of proteins, which negates the requirement of cells adhered to the surface of the claimed invention, and cites specific portions of Cherukuri as support (see page 8, 3rd paragraph).

Applicant's arguments have been fully considered, but are not persuasive. With respect to Applicant's first point above, the motivation for combining Cherukuri with Hollis is clearly presented in the previous Office Action and restated *supra* as “in order to provide a proper control and delivery system for regulating and distributing minute amounts of reagents to the reaction cells”, which is taken directly from Cherukuri. See column 2, lines 6-9. One of ordinary skill in the art would recognize that a controlled means of reagent delivery would benefit the device of Hollis since it allows for specific reagent volumes to be delivered in a controlled manner, and is proper motivation for combining the reagent delivery system of Cherukuri in the device of Hollis. In regards to Applicant's statement that “the Office Action has provided neither a line of reasoning as to why one of skill in the art would have found the invention obvious, nor any factual support for the assertion of motivation to combine”, the Examiner acknowledges that the

actual obvious statement was inadvertently omitted from the previous Office Action, but submits that by citing specific portions of Cherukuri that disclose the delivery system and advantages of such a system, the rationale for an obviousness rejection was present. In addition, Applicant is directed to page 7, 2nd paragraph of the previous Office Action, which provides clear disclosure of the motivation and line of reasoning for combining Cherukuri with Hollis.

With respect to Applicant's second point above, although the claimed invention does not require a semiconductor chip or a device with an intended use of performing combinatorial chemistry, Hollis and Cherukuri references are still proper references since they disclose in combination the claimed embodiments of the instant invention. Hollis teaches an array of wells with cell binding probes in each well, which anticipates claim 1(a). Cherukuri teaches a modular configuration of reservoirs and microchannels in specific arrangements that anticipate claim 1(b). As stated above, there is motivation to combine the two references. In addition, the claimed invention is directed to a device that binds cells in an array format and delivers reagents to an array by means of a fluid delivery system. Since Hollis teaches that the array binds cells and Cherukuri teaches a fluidic delivery system for a plurality of wells, the references are actually directly relevant to the claimed invention, regardless of other stated intended uses in the references.

With respect to Applicant's third point above, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck &*

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Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). With respect to Applicant's statement that Hollis does not provide teaching of a fluid delivery system that "mates" with the base, Applicant is reminded that Hollis is not applied to teach the fluid delivery device. Rather, Cherukuri is applied to teach the specific limitations of the fluid delivery device. Specific to the limitation "mates", Cherukuri discloses that the modular configuration comprises three plates that are "coupled together to form a liquid-tight seal". See column 2, lines 48-52. The top and center plate are considered to be part of the fluid delivery device and the bottom cell plate is where the array of Hollis would be placed. Since the plates are coupled, which is considered a type of mechanical attachment, the plates thereby "mate" and teach the claimed limitation. With respect to Applicant's statement that the claimed invention requires microfluidic channels that supply "domains matching the wells", Cherukuri once again, not Hollis, is applied to teach the fluid delivery system. Since Cherukuri teaches that "each sector on the center distribution plate is directly positioned above a reaction cell located on the bottom cell plate" (see column 3, lines 22-24), the reference properly teaches the claimed limitation. Furthermore, with respect to Applicant's citation in Cherukuri that teaches pretreatment to avoid surface adsorption, the cited portion of Cherukuri refers to the center distribution plate, which is part of the fluid delivery channels and not the binding sites of the bottom cell plate. In addition, Hollis teaches specifically that the binding sites can bind cell targets, thereby providing sufficient teaching test sites that bind to cells.

In light of the evidence presented above, Applicant's arguments are not found to be convincing and the rejections made in the previous Office Action are maintained.

Conclusion

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

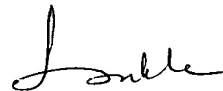
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y. Lum
Patent Examiner
Art Unit 1641



LYL



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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